

REMARKS/ARGUMENTS

The Rejections Under 35 USC § 112

The rejections to the form of the claims are overcome by amendments.

The Rejections Under 35 USC § 103

The claims are rejected as allegedly unpatentable under section 103 over the combination of Hesch, Shealy, and Campbell. (It appears from page 4 of the office action that claim 20 is allowed.)

Hesch teaches the use of androgens for treating androgen deficiency. Hesch also teaches that occurrence of benign hypertrophy of the prostate has a course that is parallel with testosterone deficiency.

Shealy teaches two ways, which can be combined, to stimulate specific points/locations of the body to raise DHEA (an androgen and androgen precursor) levels. One of the ways taught is through the topical administration of a pharmacologically effective amount to elevate the patient's serum levels of DHEA of an ointment containing progesterone to "specific locations of the patient's body." See column 3, lines 33-49. The second way is through the daily electrical stimulation applied to specific acupuncture points. See column 3, lines 63-67.

Nowhere does Shealy teach or suggest the administration of progesterone to achieve a gestagenic effect. The effect achieved by Shealy is a stimulation effect of specific locations of the body to achieve an androgenic effect, i.e., increase endogenous DHEA levels. Shealy does not even hint that gestagenically effective amounts of any gestagen should be administered.

Thus, the cited combination of references leads to a combination of two androgenic effects, not androgenic and gestagenic effects in the context of the claims. If anything, the prior art teaches away.

The Office Action alleges that it would have been within the skill of those in the art to select optimal parameters such as doses, etc. This is a bare allegation as applied to the claims here, which ignores the teachings of the references. Shealy specifically teaches that the amount to be applied is "in a pharmacologically active amount, on a daily basis for a sufficient time, to elevate the patient's serum DHEA levels." See column 3, lines 45-50. Selecting optimal levels within the range taught by Shealy may not provide sufficient basis for patentability of such

optimized range, although this is not admitted, but selecting ranges not taught or suggested by Shealy, i.e., a gestagenically effective amount of a gestagen, is not merely selecting optimal parameters from the teachings of Shealy. One of ordinary skill in the art following the teachings of Shealy would know that in order to achieve the desired goal of raising DHEA levels, the amount to be administered has to be a pharmacologically active amount to work through the specific locations for the stimulation of DHEA production. See column 3, lines 30-50. Nothing in Shealy teaches or suggests to one of ordinary skill in the art to administer a gestagenically effective amount of a gestagen, which therefore is not obvious from the teachings of this reference.

The Office Action cites to *In re Boesch*, 205 USPQ 215 (CCPA 1980), in making the allegation that the optimization of parameters is within those of skill in the art. However, *Boesch* is not applicable to this case because the principle followed by the court therein does not fit the facts here. The court in *Boesch* followed the “rule that discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art.” See *id.* In Shealy the result is the elevation of DHEA levels; and thus, under the *Boesch* principle ordinarily it would be within the skill of the art for one to optimize for the range effective to achieve such elevation of DHEA levels. That is, one of ordinary skill in the art following the teachings of Shealy would be motivated only to optimize for an amount of progesterone cream that achieves elevated levels of DHEA, i.e., such artisan would look at the desired result (levels of DHEA) when making a selection for optimized doses of progesterone.

The purpose/effect of the claimed dosage is very relevant to the determination of whether the claimed invention is obvious. Consider the following excerpt from *In re Fine*, 5 USPQ2d 1596 (CAFC 1988)

The claimed nitric oxide conversion temperature is not disclosed in Warnick. Although Eads describes a preferred temperature of 675°C to 725°C, the purpose of this range is different from that of Fine. Eads requires the 675°C to 725°C range because it affords a temperature low enough to avoid formation of unwanted sulfur trioxide, yet high enough to avoid formation of unwanted sulfides. Fine's temperature range, in contrast, does not seek to avoid the formation of sulfur compounds or even nitrogen compounds. It enables the system to break down the nitrogen compounds of the sample while avoiding the destruction of background nitrogen gas. There is a partial overlap, of course, but this is mere happenstance.

Because the purposes of the two temperature ranges are entirely unrelated, Eads does not teach use of the claimed range. (Emphasis added.)

Additionally, it is well settled that the “consideration of the problem facing the inventor is an element of perceptive analysis of whether the invention as a whole would have been obvious to a person of ordinary skill.” See *In re Dillon*, 13 USPQ2d 1337 (CAFC 1989). The present inventors were working/solving a problem other than Shealy, which is concerned with methods to elevate DHEA levels by stimulating specific locations of the body.

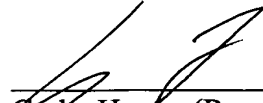
Campbell teaches transdermal delivery systems for drugs such as testosterone and progesterone. Exemplified are systems for delivery of testosterone, which can be used in testosterone replacement therapy. Nowhere does this reference teach or suggest the claimed method or add anything new to the first two references relevant for the rejection.

Moreover, applicants bring the attention of the Examiner to the data provided in the specification on pages 9-14. The experiment and data disclosed on pages 12-14 demonstrate the use of several of the claimed combinations in achieving inhibiting prostate growth. As can be seen, the administration of testosterone alone (androgen alone) leads to an increase in prostate weight. The administration of an androgen/gestagen combination reduces the androgen-produced increase of the prostate weight. The experiment and data disclosed on pages 9-11 demonstrate the use of the claimed combinations in achieving inhibition of androgen-dependent cell proliferation of a prostate-cancer-cell line. As can be seen, the administration of the androgen alone induces cell growth. The administration of the second component gestagen inhibits the androgen-dependent cell proliferation of the prostate-cancer-cell line. These combinations are not taught or suggested by the prior art which suggests only combining two androgenic effects.

Reconsideration is respectfully requested.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



Csaba Henter (Reg. No. 50,908)
Anthony J. Zelano (Reg. 27,969)
Attorneys for Applicant(s)

MILLEN, WHITE, ZELANO
& BRANIGAN, P.C.
Arlington Courthouse Plaza 1, Suite 1400
2200 Clarendon Boulevard
Arlington, Virginia 22201
Telephone: (703) 243-6333
Facsimile: (703) 243-6410

Filed: September 21, 2005

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